

REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 50-0311. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

AMENDMENTS TO THE SPECIFICATION

The Office Action objects to the first paragraph of the specification for not including the updated status of the co-pending applications. The amendments to the specification herein satisfy these requirements. No new matter is added.

AMENDMENTS TO THE CLAIMS

Claims 1, 25, 27, 46, 49, 53, 54 and 57 are amended herein. Claims 18, 45, 48, 50, 51, 52, 58 and 60-69 are cancelled herein. Claims 70-77 are added herein. No new matter is added.

The Office Action stated that claims 16, 18, 38-41, 43, 44, 48, 50 and 56-58 would be allowable if rewritten in independent form. Claims 16, 18, 38, 43 and 58 drawn to the allowable subject matter are rewritten in independent form herein. Claim 1 is amended to incorporate the allowable subject matter of claim 18. Amended claim 54 incorporates the allowable subject matter of claim 58. New claim 70 incorporates the allowable subject matter of claim 16 and the subject matter of original base claims 1 and 15. New claim 72 incorporates the allowable subject matter of claim 38 and the subject matter of original base claim 1. New claim 76 incorporates the allowable subject matter of claim 43 and the subject matter of original base claim 1. No new matter is added.

The amendments to claims 25 and 27 provide clarity by distinguishing between the struts of the retainer region and the struts of the valve protector region in view of the amendments made to base claim 1. The amendments to claims 46, 49 and 53 correct claim dependency errors that resulted due to the claim cancellations herein. No new matter is added.

The amendments to the claims render the rejections under 35 U.S.C. §§ 102(b) and 103(a) moot.

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential elements. The Office Action alleges that the applicant has disclosed

intended use of but does not claim that the duckbill valve includes a small channel opening that allows flow in both directions. We respectfully disagree.

Claim 8 is directed to the flow control device of claim 1, wherein the "valve member blocks fluid flow in both an inhalation direction and in an exhalation direction." The specification provides support for a valve member that does not allow fluid to flow in any direction (see, for example, page 31, lines 2 - 7):

"...With reference to Figure 6, the valve member 620 is disposed within the valve protection portion 720 of the frame 615. The valve member 620 can be configured to either permit fluid flow in two directions (i.e., proximal and distal directions), permit fluid flow in only one direction (proximal or distal direction), **completely restrict fluid flow in any direction** through the bronchial isolation device 610, or any combination of the above....[emphasis added]"

Claim 1 specifies the valve member "regulates fluid flow through the flow control device". Regulating fluid flow can mean allowing flow through the device or not allowing flow through the device. For example, the specification at page 10, lines 10-13 states "...bronchial isolation devices 610 **block or regulate fluid flow** to the diseased lung region through one or more bronchial passageways that feed air to the targeted lung region...[emphasis added]" In this context "regulate" can mean "block" fluid flow. Thus, neither claim 8 nor its base claim 1 specifies that the valve member is a duckbill valve that includes a small channel opening that allows flow in both directions. This is not an essential element as alleged by the Office Action.

We believe that all the claims are now in condition for allowance. Reconsideration and allowance of the above-referenced application are respectfully requested.

* * *

It is believed that all of the pending claims have been addressed in this paper. However, failure to address specific rejection, issue, or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as intent to concede any issue with regard to any claim, except as

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
specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The claims are in condition for allowance, and a notice to that effect is respectfully solicited. If the Examiner has any questions regarding this response, the Examiner is invited to telephone the undersigned at (858) 320-3018.

Please apply any charges not covered, or any credits, to Deposit Account No. 50-0311.

Respectfully submitted,

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